IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

ANTHONY DeGIDIO,	)	
	)	CASE NO. 3:09-CV-00721
Plaintiff,	)	
	)	JUDGE JAMES G. CARR
v.	)	
CENTOCOR, INC., et al.,	)	
Defendants.	)	

PLAINTIFF'S SURREPLY IN OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Pamela A. Borgess (0072789)
ZOLL, KRANZ & BORGESS, LCC
6620 W. Central Avenue, Suite 100
Toledo, Ohio 43617
Phone: 419-841-9623
Fax: 419-841-9719
Email: pamela@toledolaw.com

Attorneys for Plaintiff

TABLE OF CONTENTS

TABLE OF AUTHORITIES

ARGUMENT

I. DEFENDANTS' ENLARGEMENT OF THEIR SUMMARY JUDGMENT MOTION TO INCLUDE ISSUES BEYOND WHETHER THE REMICADE® LABEL UNAMBIGUOUSLY WARNS OF THE PLAINTIFF'S CONDITION AS A MATTER OF LAW IS IMPROPER, PREMATURE, AND CONTRARY TO THE COURT'S SCHEDULING ORDER.

At the commencement of this litigation, in the initial Case Management Conference on July 6, 2009, Defendants asserted to this Court that its Remicade® label clearly and unequivocally warned of Plaintiff's injury on its face. Specifically, Defendants argued that the warning's multiple references to "pneumonia" unambiguously included Plaintiff's injury.

In response this assertion and in the interests of judicial economy and convenience, the Parties and Court agreed upon a Scheduling Order which would allow the Parties, well in advance of completion of discovery and the disclosure of experts, to brief this specific threshold issue of the facial sufficiency of the Remicade® warning as a matter of law. (R.19.) Pursuant to the Court's Order, the deadline for filing this initial dispositive motion was April 1, 2010. This deadline, however, was delayed until June 1, 2010 due to scheduling conflicts which necessitated the rescheduling of the key deposition of Plaintiff's prescribing and treating physician, Dr. Gregory Slee, a gastroenterologist. (R.19; R.27.)[1] The briefing on this motion is just now being concluded, with oral argument to occur on September 27, 2010.

Thus, the **only** issue properly addressed by the initial dispositive motion is whether the Remicade® label specifically and unambiguously warns of the condition suffered by the Plaintiff **as a matter of law**. Again, expert reports were not even intended to be produced by either party

[1] Defendants did not seek to depose Plaintiff's treating Pulmonologist, Dan Olson, MD, PhD, whose declaration has since been filed with Plaintiff's Motion to File a Supplemental Exhibit to his Opposition, which is currently pending before this Court. Dr. Olson is a medical expert who specializes in interstitial lung disease, the exact condition at issue. Plaintiff endeavored in good faith to provide Dr. Olson's declaration contemporaneously with his Opposition Brief, but was unable to do so due to Dr. Olson's absence from the country and busy surgical schedule. As such, Plaintiff has requested leave to supplement his opposition with said declaration. (R.42.)

until well after the conclusion of briefing on this preliminary issue.[2] If this Court determines that the label does not specifically and unambiguously warn of the condition suffered by the Plaintiff as a matter of law, the case would then to proceed to the second and main issue regarding whether or not such warning **should** have been included (i.e. whether Defendants knew or should have known of the causal relationship between Plaintiff's injury and the drug, and thus, should have warned of such.)

As described in the next section of this Surreply, Plaintiff has absolutely produced sufficient and undisputed evidence, including testimony of at least one medical expert (who is also Plaintiff's prescribing and treating physician), and the declaration of another, to establish that the warning label on its face, does not warn users or their healthcare providers of the specific condition suffered by Plaintiff as a matter of law. Specifically, the undisputed expert testimony is that: (1) Plaintiff was diagnosed with a specific type of non-infectious interstitial lung disease (NILD), "Remicade-induced, eosinophilic pneumonitis with no clear infectious etiology;" (2) The label specifically warranted in the post-approval section that a causal relationship had not and/or could not be established between NILD and Remicade®; (3) The label refers solely to infectious pneumonia, not NILD; (4) Infectious pneumonia is a distinctly different medical condition from non-infectious lung disease, NILD, and in fact, the two conditions have opposite treatments.[3]

[2] As a result of the extension of the initial dispositive motion deadline and briefing schedule, Plaintiff has requested an extension of the remaining deadlines. Defendants have acknowledged that should this Court "deny Defendants' pending Motion for Summary Judgment, or otherwise determine that this case should proceed to another stage of dispositive motion briefing, Defendants agree that an extension to the dates in the current case management schedule would be necessary." (R.43) Further, Defendants "do not object to Plaintiff's proposed new dates under those circumstances, and, accordingly, would agree with moving all dates forward by the same amount of time to maintain the deadline intervals originally established by the parties." (*Id.)*

[3] In this case the wording of the warning is extremely important. The warning for infectious pneumonia coupled with the lack of a warning for NILD prevented Plaintiff's physicians from reaching a correct diagnosis and greatly

It is telling that in response to this evidence, Defendants did not present any expert testimony of their own. They did not provide this Court with an affidavit from any medical expert contradicting Plaintiff's diagnosis. Similarly, they did not provide this Court with an affidavit from any medical expert verifying the position they first argued to this Court in its initial case management conference, that the warning's pneumonia warnings include Plaintiff's diagnosis. The **only** basis that Defendants have for their argument that the label's infectious pneumonia warnings include Plaintiff's condition, is their own bare assertion to such. Certainly if such evidence existed, Defendants would have provided it.[4]

Apparently recognizing their inability to refute this evidence, Defendants' briefs, most notably their Reply Brief, assert numerous grounds for summary judgment beyond the preliminary issue of whether the Remicade® label specifically and unambiguously warns of the condition suffered by the Plaintiff as a matter of law. For example, on page five of their Reply, Defendants argue that summary judgment should be granted as "Plaintiff does not provide any expert testimony concerning the incidence or prevalence of interstitial pneumonia, specifically EP, and no federal regulatory documents concerning such a risk, including any requirement for additional warning." (R.39 at 5.) However, this issue was intended to be addressed at a latter stage in this case, after the completion of discovery and the exchange of expert reports, and by the deadline established for the filing of the second round of dispositive motions. The overbroad motion filed by Defendants, who now conveniently cannot recall the intention of the parties and

---

delayed Plaintiff's treatment for NILD. This delay was nearly fatal for Plaintiff and resulted in permanent injuries, including paralysis, and 24-hour-a-day dependence on an oxygen tank.

[4] The only testimony relied on by Defendants is that of Dr. Slee, a gastroenterologist, who played no role in diagnosing Plaintiff's injury. However, Dr. Slee, as a physician who has prescribed Remicade® and was familiar with its label, testified that he was unaware of Remicade®-induced NILD prior to Plaintiff's battle with NILD and, therefore, could not have warned Plaintiff of that life-threatening adverse reaction.

Court in setting its Scheduling Order, is simply an unfortunate attempt to sandbag Plaintiff and attempt to deprive him of a full opportunity to discover all facts supporting his claims.

Summary judgment is not appropriate as to whether the Remicade® label specifically and unambiguously warns of the condition suffered by the Plaintiff as a matter of law. To the extent, however, that this Court wishes to consider premature arguments concerning whether Defendants knew or should have known of the causal relationship between Plaintiff's injury and the drug, and thus, should have warned of such, Plaintiff again respectfully requests that this Court hold its decision in abeyance pending the completion of all discovery, thereby consolidating the two dispositive motion deadlines into the later date.

II. THE REMICADE® WARNING LABEL, ON ITS FACE, DOES NOT WARN USERS OR THEIR PRESCRIBING PHYSICIANS OF THE SPECIFIC CONDITION SUFFERED BY PLAINTIFF AS A MATTER OF LAW.

A. Plaintiff's injury.

There is no dispute as to Plaintiff's condition. Plaintiff was diagnosed with a specific type of non-infectious interstitial lung disease ("NILD"), "Remicade-induced, eosinophilic pneumonitis with no clear infectious etiology." (*See* R.35 Ex. 1, Ex. 2 at 158.) The healthcare providers all concur with this diagnosis. (R.35 Ex.2 at 190-91. *See also* Olson Declaration, ¶¶4-6, attached as Ex. 11 to R.42.) Defendants have offered no evidence, medical or otherwise, that contradicts this diagnosis other than the testimony of Dr. Slee, who admits that he was unaware of Remicade®-induced NILD, even after multiple readings of the drug's label.

B. The Remicade® label specifically warrants in the post-approval section that a causal relationship has not and/or cannot be established between NILD and Remicade®.

The Remicade® label's "post-approval" section (never quoted in their original brief by Defendants) states:

> The following adverse events have been reported during post-approval use of REMICADE® . . . **interstitial pneumonitis**/fibrosis . . . Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency **or establish a causal relationship to REMICADE® exposure**.

(R.35, Ex.3. at 44 [emphasis added]).

Prescribing physician, Dr. Slee, testified as follows:

Q. I want you to look at the entire exhibit, Number 5 and tell me if you believe that this medication guide warns of a known association between the use of Remicade® and EP, eosinophilic pneumonia which is a type of interstitial lung disease?

MR. TABER: Objection.

A. Not to my knowledge or reading.

***

Q. [L]ater the last sentence states, "Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relation to Remicade® exposure." Did I read that correctly?

A. Yes.

Q. So you would agree that on page 28 of Plaintiff's Exhibit 5, the drug company specifically warranting in this provision that although there has been some reports post market, it cannot or has not determined whether there is, in fact, some causal relationship between Remicade® and interstitial pneumonitis?

MR. TABER: Objection.

A. That's what it says to my reading, yes.

***

Q. So let's then go back to my question about whether or not this revised April 2007 medication guide warns of any known association between the use of Remicade® and EP, a type of interstitial lung disease?

MR. TABER: Objection.

A. I haven't seen it in here.

***

Q. And if we turn to page 44 of Plaintiff's Exhibit 4, we see the same language regarding "Post-marketing Adverse Events", correct?

A. Yes.

Q. And, again, we see a warranty from the drug company, that although there has been some reports of interstitial pneumonitis post-market that it cannot or has not determined whether there is, in fact, some sort of causal relationship?

MR. TABER: Objection to the characterization.

A. The language hasn't changed and doesn't indicate to my read a causal relationship.

Q. Doctor, were you ever provided any warnings by the drug company either orally or in writing that Remicade® had a known relationship with interstitial lung disease or EP?

MR. TABER: Other than what? Objection.

A. No.

(R.35 Ex. 2 at 196-200.) (*See also* R.35 Ex.10.)

Defendants have offered no evidence, medical or otherwise, that contradicts Dr. Slee's testimony or his plain reading of the label.

C. The Remicade® label's references to pneumonia refer solely to infectious pneumonia, which is a distinctly different medical condition from NILD.

It is undisputed that the label's references to pneumonia refer only to infectious pneumonia and that Plaintiff's condition, NILD, is not the same medical condition as infectious pneumonia. (See R.35 Ex.1, Ex. 2 at 158, 192, Ex. 10, Ex. 11.) Indeed, the two conditions have opposite treatments in terms of their reaction and response that they elicit in the body. The treatment for NILD/EP is steroids, which is contraindicated for an infectious pneumonia as it causes the "pneumonia to flourish". (R.35 Ex. 2 at 192.) The treatment for infectious pneumonia, the type referred to by the Remicade® label, is antibiotics. The antibiotics kill the pathogen and thus, would have no effect on NILD. (R.35 Ex. 10, Ex. 11.) Dr. Slee testified as follows:

Q. I want you to look at the entire exhibit, Number 5 and tell me if you believe that this medication guide warns of a known association between the use of Remicade® and EP, eosinophilic pneumonia which is a type of interstitial lung disease?

MR. TABER: Objection.

A. Not to my knowledge or reading.

Q. What type of pneumonia does Defense Exhibit 5 warn of?

A. It warns of the infectious types of pneumonia. Various and many infectious types of pneumonia.

***

Q. So let's then go back to my question about whether or not this revised April 2007 medication guide warns of any known association between the use of Remicade® and EP, a type of interstitial lung disease?

MR. TABER: Objection.

A. I haven't seen it in here.

Q. And, again, what is the type of pneumonia that is warned about in Defense Exhibit 4?

A. Infectious type pneumonia.

(R. 35 Ex. 2 at 196, 199.)

Q. In this particular case we didn't have an infectious etiology and I believe that's consistent with your earlier testimony?
MR. TABER: Objection.
A. Yes. I found none. Their review found none.***

(*Id.* at 193.)

A. There was no infection. Therefore, his immunocompromised state may have hurt him in a way, but it didn't hurt him setting up an infection. He had none.
Q. He had one at Michigan for sure?
A. Oh, yeah. But that's because of this first problem, the interstitial lung disease. The reason the three antibiotics didn't work, the reason the IV antibiotics didn't work in the hospital, the reason the antifungal antibiotic didn't work is he had no infection.
Q. And have you reviewed all of those records or just the biopsy records?
A. The biopsy records.
Q. So you were not personally involved with any of the medical-
A. (Interposing) Michigan knows that he didn't have any infection. They reviewed the biopsies. That's why they started him on steroids because he had no infection.
Q. Okay. So --
A. The reason that he had a first biopsy within 24 hours of hitting the hospital was to see if he had an infection because nothing was working. He did not. They were so concerned about that they took him to an open lung biopsy, a huge move. He had no infection. So his immunocompromisation played a role in making him sick, but it didn't give him an infection that he didn't have.

(*Id*. at 156-57.)

To the extent this Court permits supplementation of the declaration of Pulmonologist, Dan Olson, MD, PhD, (see FN 1), Dr. Olson concurs with Dr. Slee, stating as follows:

7. Drug-induced eosinophilic pneumonitis with no clear infectious etiology is not the same as opportunistic infectious pneumonia and is considered to be a non-infectious pneumonia.

8. There are many differences between infectious and non-infectious pneumonias. Non-infectious diseases (also called Non-communicable diseases) are those diseases that are not caused by a pathogen and cannot be shared from one person to another.

> 9. Infectious disease is caused by organisms e.g., virus, bacteria, fungus, mycoplasma, and parasites (among others) which can get transmitted to other people. AIDS, tuberculosis, cholera, sexually transmitted diseases, herpes, are all examples of infectious diseases.
>
> 10. Non infectious diseases include auto-immune problems like Crohn's disease, arthritis, psoriasis. They also include health problems such as trauma, burns, animal and human bites, genetic diseases, some types of cancers, psychiatric and psychological illnesses, strokes and paralysis, heart attacks, COPD lung cancer secondary to smoking, liver failure secondary to alcohol, drug addictions, poisoning, suicide, obesity, etc. These are usually not secondary to an organism and are not contagious i.e., transmissible from one person to another.

> 11. Further, the treatment for Remicade-induced eosinophilic pneumonitis is different from the treatment for opportunistic infectious pneumonia, including, for example, the use of corticosteroids, rather than antibiotics.

(Ex. 11 ¶¶7-11, attached to R.42.) Indeed, this important distinction is evidenced by the multiple failed attempts of Plaintiff's physicians to treat what they initially and erroneously believed, based on the Remicade® label, was infectious pneumonia, rather than NILD.

Defendants offer no evidence, medical or otherwise that contradicts this testimony.

III. THE UNSUPPORTED AND OVERBROAD ARGUMENTS RAISED BY DEFENDANTS DO NOT WARRANT THE GRANTING OF SUMMARY JUDGMENT.

A. Plaintiff does not lack expert testimony.

Defendants' first argument in their reply is a prime example of how they have purposefully merged the intended preliminary issue (i.e. whether the Remicade® label specifically and unambiguously warns of the condition suffered by the Plaintiff as a matter of law), into the latter issue to be decided after the exchange of experts and completion of

discovery, (i.e. whether Defendants knew or should have known of the causal relationship between his injury and the drug, and thus, should have warned of such).

Defendants allege that Plaintiff's claim should fail as he "has not offered any expert support." However, as reiterated above, the record is clear that he has in fact proffered expert testimony showing that the Remicade® label on its face, does not warn users or their prescribing physicians of NILD as a matter of law.

Faced with this testimony, Defendants misconstrue Plaintiff's burden at this point in the litigation, arguing that Plaintiff has not produced expert testimony on a subsequent issue; that the label is inadequate because it **should have** included a warning regarding a known causal relationship with NILD. In support of this contention, Defendants' state that Dr. Slee, during his deposition, testified that the Remicade® label was "adequate." However, Defendants' argument is a mischaracterization of both the scope of this initial dispositive motion and the testimony of Dr. Slee.

Dr. Slee has a wealth of experience in prescribing and administering Remicade®. As set forth above, during his deposition Dr. Slee clearly stated that the Remicade® label did not inform him of the existence of a known causal relationship between the drug and the development of NILD. As such, and as to be expected, Dr. Slee testified that he was unaware of any known causal relationship between the two. Interestingly, while Defendants rely heavily on portions of Dr. Slee's deposition testimony, they offer no explanation as to why, if the Remicade® label is clear on its face, Dr. Slee was unaware of a Remicade®-NILD link.

During direct, defense counsel asked Dr. Slee if he believed the drug label was "adequate," to which he responded in the affirmative. However, as established on cross, Dr. Slee indicated that he was not privy to any of Defendants internal testing, investigation, or studies that

may have been conducted to determine the likelihood or the numerosity of incidents of interstitial lung disease as a result of Remicade® use. Further, he had not independently conducted any tests regarding any relationship between the two. Thus, he clarified that his earlier testimony that the drug label was adequate was based **solely** on the information provided to him by Defendants, which he could not dispute given his lack of any knowledge as to the relationship between NILD and Remicade®. (R.35 Ex.2 at 202-203.)

The preliminary issue in Defendants' initial dispositive motion was only meant to address whether the warning is unambiguous as a matter of law.[5] As Plaintiff has shown that the Remicade® warning does not warn on its face of NILD as a matter of law, Defendants' Motion for Summary Judgment should be denied and Plaintiff should be allowed to proceed to the next phase of the discovery regarding to whether Defendants knew or should have known of the causal relationship between his injury and the drug, and thus, should have warned of such.

B. Dr. Slee's testimony establishes that he would have provided warning to Plaintiff regarding NILD, if such warning had been included.

In their next argument, Defendants again improperly merge the preliminary issue in this initial dispositive motion with the subsequent issue regarding whether such warning **should have**

[5] Indeed, although Plaintiff has provided expert testimony to assist this Court, such testimony is not even required for issues concerning interpretation of a document as a matter of law. Rather, when language in a document "is unambiguous, its construction is a matter of law for the court and 'expert' explanation is unnecessary and unwarranted." *Ruschel v. Nestle Holding, Inc.*, Nos. 89977, 90500, 2008 WL 1903856, *4, ¶26 (Ohio App. 8 Dist., May 1, 2008), citing *Union Elec. Co. v. Metro. St. Louis Sewer Dist.*, No. ED88123, 2007 WL 1341820 (Mo.App. E.D. May 09, 2007); *Sheet Metal Workers, Local Union No. 24 v. Architectural Metal Works, Inc.*, 259 F.3d 418, 424 (6th Cir 2001). Defendants' cite *Saraney v. Tap Pharmaceutical Prod.*, 2007 WL 148845 (N.D. Ohio 2007), in support for their blanket claim that "[t]o survive summary judgment, however, Plaintiff must establish the inadequacy of any warning through expert medical testimony." (R.39 at 2-3.) However, in *Saraney*, Tap Pharmaceutical moved for summary judgment **after the conclusion of fact and expert discovery**, and following the plaintiffs' failure to designate a **single expert to support any of their claims**. *Id.* at *1. Furthermore, the pharmaceutical at issue in the case, Lupron, provided a package insert that repeatedly warned of the **exact same adverse reaction** as was the subject of the plaintiff's claims. *Id* at *6. As the drug's warning was determined by the court to be absolutely clear on its face, the lack of expert testimony was merely an additional and not dispositive factor warranting the granting of summary judgment. *Id*.

been included. Defendants also again mischaracterize Dr. Slee's testimony. As previously asserted in their motion, Defendants argue that summary judgment is appropriate because Dr. Slee testified that he "probably would not" have communicated any warning of NILD to his patients. However, as set forth in Plaintiff's Opposition Brief, the portions of the transcript cited by the Defendants were taken out of context and do not accurately portray Dr. Slee's position. (As the full testimony was already quoted on pages 24-26 of Plaintiff's Opposition Brief, it will not be repeated herein.) Dr. Slee clarified later in his deposition that he indicated that he "probably would not" have communicated a warning as he was unaware of any relationship based on the information provided to him. However, had he received warning from Defendants of an established and significant risk of Remicade-induced NILD, such that it should have been in the label, it "absolutely would have been something that [he] would have provided in addition to the other warnings given to patients." (R.35 Ex.2 at 204.)

In their Reply brief, Defendants respond to Dr. Slee's testimony clarifying his position (which they had conveniently omitted from their earlier motion), by arguing that Plaintiff has not yet proven an established or significant risk which would have required inclusion on the label. Thus, Defendants argue that any testimony by Dr. Slee that he would have passed on a NILD warning had it been included, (as he did with all warnings) is merely a "hypothetical." However, again, the present issue to be decided by this Court does not concern whether the risk was known and/or significant enough to have warranted inclusion on the label. The issue, at this point in the litigation, solely concerns whether the label is clear on its face as a matter of law. As such, Defendants' contention that Dr. Slee's deposition testimony is irrelevant because it was in response to "a hypothetical" should be disregarded by the Court.

C. The Remicade® label's sole reference to NILD in the "post-approval" section does not constitute a warning, but rather warrants to users and their prescribing physicians that a causal relationship has not and/or cannot be established between NILD and Remicade®.

In their motion for summary judgment, while referencing their infectious pneumonia warnings, Defendants never quoted the following "post-approval" section below:

> The following adverse events have been reported during post-approval use of REMICADE® . . . **interstitial pneumonitis**/fibrosis . . . Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency **or establish a causal relationship to REMICADE® exposure**.

(R.35 Ex.3 at 44 [emphasis added]). Likewise, Defendants failed to mention Dr. Slee's repeated testimony that he read these sections as specifically indicating that although there had been some reports of interstitial pneumonitis post-market, it had not or could not determined whether there was, in fact, some sort of causal relationship to NILD.

In their Reply, Defendants now refer to this provision as a "warning." This interpretation, however, is contrary to that held by Dr. Slee. Apparently, this alleged "warning" was also missed by Plaintiff's other physicians, including Dr. Miller (Plaintiff's PCP) and Dr. Horton (the pulmonary doctor at Toledo Hosp.). These physicians all initially concentrated on trying to identify a pathogen due to the known relationship between Remicade® and infectious pneumonia and were unaware of a causal relationship between NILD and Remicade® after reading the drug label.

Defendants then spend two and a half pages in their Reply arguing that this "warning" cannot be used as evidence "to establish causation." However, this argument misses the point. Plaintiff is not relying on the "post approval" section "to establish causation." Indeed, specific causation of Plaintiff's Remicade-induced injury is undisputed. Similarly, Plaintiff is not relying on this section alone to establish that Defendants knew or should have known of the causal

relationship between Plaintiff's injury and the drug, and thus, should have warned of such. This is an issue for a later date. Instead, this provision is being cited for its relationship to the specific issue of law before this Court: whether Remicade® label specifically and unambiguously warns of the condition suffered by the Plaintiff, NILD, as a matter of law.

D. Plaintiff's fraud and conspiracy claims are not abrogated by the OPLA.

In Defendants' initial Brief, they claimed that summary judgment was warranted on Plaintiff's fraud and civil conspiracy claims because, respectively, Plaintiff could point to no evidence of any misrepresentation made by the Defendants regarding the safety of Remicade® or any underlying tortuous conduct by Defendants. (R.29 at 19-24.) Defendants also claimed that Plaintiff's conspiracy claim was abrogated by the Ohio Products Liability Act. (*Id*. at 26.) In their Reply Brief, Defendants now claim that, not only is the conspiracy claim abrogated, but Plaintiff's fraud claim as well.[6] (R.40 at 10-13.) Although Defendants restate their argument for abrogation in their Reply, their refrain carries no more weight or authority than it did initially and should be disregarded by this court.

As support for the abrogation of Plaintiff's claims Defendants cite two recent decisions by the Northern District which, they claim, support their position that fraud and conspiracy are subject to abrogation pursuant to O.R.C. §2307.71. However, neither case provides any support for the Defendants' claim.

[6] This new argument, as well as any others raised by the Defendants for the first time in their Reply should be disregarded by this Court. The Sixth Circuit has repeatedly recognized that arguments initially raised in a party's reply brief are waived. See, e.g., *United States v. Lopez-Medina*, 461 F.3d 724, 743 (6th Cir. 2006), citing *McPherson v. Kelsey*, 125 F.3d 989, 995-96 (6th Cir. 1997) (deeming arguments not raised in the appellant's main brief, or raised merely in a perfunctory manner, to be waived); *Lexicon, Inc. v. Safeco Ins. Co. of America, Inc*., 436 F.3d 662, 676 (6th Cir. 2006) (holding that a district court properly declined to consider an issue raised for the first time in a reply brief), citing *Sundberg v. Keller Ladder*, 189 F.Supp.2d 671, 682-83 (E.D. Mich. 2002) (noting, in the context of summary judgment, "it is not the office of a reply brief to raise issues for the first time").

In *Crisp v. Stryker Corp.*, No. 5:09-cv-02212, 2010 WL 2076796 (N.D. Ohio, May 21, 2010), the Court's decision to dismiss the Complaint with leave to refile, was largely administrative in nature as the plaintiff's original action was instituted through the filing of a multi-party, multi-jurisdiction Complaint. *Crisp*, 2010 WL 2076796 at *4. Furthermore, the decision of the Court contained no discussion of whether the plaintiff's fraud claim was, in fact, abrogated by the OPLA.

Defendants' reliance on *Friedman v. Intervet, Inc.*, No. 3:09-cv-2945, 2010 WL 2817257 (N.D. Ohio July 16, 2010), is similarly misplaced. As this Court is well aware, the citation relied on by Defendants: "[t]o be sure, the OPLA preempts all claims that might arise under Ohio common law and statutes" is not a holding in the case and does not reference anything more than the broad policy enunciated in its legislative history. *Friedman*, 2010 WL 2817257 at *6. Also, this sentence was made in the context of the Court's decision concluding that the OPLA did not preempt causes of action arising under New Jersey's Products Liability Act. *Id*. The Court, in its decision, never analyzed whether fraud and the conspiracy to commit fraud constituted "common law products liability actions" subject to abrogation under the OPLA.

As the Southern District clearly and unequivocally held, "actions for fraud and negligent misrepresentation [are] outside the scope of the OPLA's abrogation, as neither fit neatly into the definition of a "common law product liability claim."" *CCB Ohio LLC v. Chemque Inc.*, 649 F.Supp.2d 757, 763-64 (S.D. Ohio 2009). Likewise, Plaintiff's claim for civil conspiracy stemming from the agreement of Defendants to engage in fraudulently misrepresenting the causal link between Remicade® use and the development of aggressive NILD is also not a "common law products liability claim." Defendants ask this Court to "read tea leaves" of

unrelated opinions and reach a conclusion completely contrary to the express holding of another district, reached after briefing and oral argument on the exact issue now before this Court.

Perhaps realizing the flaws of their argument, the Defendants' proffer that Plaintiff's fraud and conspiracy claims should still be abrogated because the "substance of the claim[s]" sound in common law products liability and are, thus covered by the OPLA. This reasoning is also incorrect. The key facet of Plaintiff's allegations is not that Defendants failed to warn Plaintiff, but that they engaged in an agreement to knowingly mislead Plaintiff and the medical community about the causal link between Remicade® use and NILD. These intentionally tortuous actions move the Plaintiff's claims out of the realm of the common law products liability claims preempted by the OPLA. The Court should reject Defendants' flawed arguments and deny summary judgment on these issues.

CONCLUSION

For the foregoing reasons, this Court should deny the Defendants' Motion for Summary Judgment.

Date: September 13, 2010

Respectfully Submitted,

/s/ Pamela A. Borgess .
Pamela A. Borgess (0072789)
ZOLL, KRANZ & BORGESS LLC
6620 W. Central Avenue, Suite 100
Toledo, Ohio 43617
pamela@toledolaw.com
Phone: (419) 841-9623
Fax: (419) 841-9719
Attorneys for Plaintiff

LOCAL RULE 7.1(F) CERTIFICATION

I certify that that this case has been assigned to the complex track and that it adheres to the page limitations set forth in LR 7.1(f), as modified by this Court in its February 2, 2010 entry.

/s/ Pamela A. Borgess .
Pamela A. Borgess (0072789)

CERTIFICATE OF SERVICE

I hereby certify that on September 13, 2010, a copy of the foregoing was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

/s/ Pamela A. Borgess .
Pamela A. Borgess (0072789)